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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/549,937	CHANCELLOR ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *107,109-112,114 and 154-217* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *107,109-112,114,154-217* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 107, 109-112, 114, 154-217 are pending.

Applicants' traversal, the amendment to claims 107, 111, 112, 114, and the addition of new claims 154-217 in paper filed on 9/27/04 is acknowledged and considered.

Information Disclosure Statement

The examiner considered the co-pending U.S. applications, but did not consider the WO documents cited on the IDS filed on 5/13/04. In addition, the examiner did not initial the U.S. applications and WO documents listed on the IDS (PTO-1449) because the co-pending U.S. applications are not considered published documents and the applicants have not provided a copy of the co-pending U. S. applications and the WO documents listed on the IDS. See MPEP 609 (37 CFR 1.98).

Claim Objections

Claim 217 is objected to because of the following informalities: the term "and/or" on line 6 is an improper term for listing a group or species. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107, 109-112, 114, and 154-217 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation '15 to 40%' in amended claims 107, 111, 112 and 114, and claims dependent therefrom (claims 109 and 110) and new claims 154-217 is not supported by the as-filed specification. See MPEP § 2163.06. Applicants cite page 28-page 29 of the instant specification and the isolation method in '896 application at page 81, Example 11 (incorporated by reference in the instant specification) for support of the new limitation. Page 28-29 from the instant specification recite preparing MDCs using the method taught in '896 and does not support the new limitation. Page 81 of '896 is directed to studying several growth factors on myoblast proliferation and fusion in vitro and evaluate muscle healing following injury. Page 81 does not support the new limitation. Example 11 of '896 supports the limitation "15-20%" and does not support the limitation '15 to 40%' in the pending claims.

In addition, the limitation 'the cutaneous depression, wound, fissure or opening in an individual' in new claim 212 and claims dependent therefrom (claims 213-215) is not supported by the as-filed specification. See MPEP § 2163.06. Applicants cite page 20, line 20-page 21, line 6 of the instant specification for support of the new limitation. However, page 20 and 21 do not provide support the limitation in new claim 212. These pages only provide support for cutaneous depression.

In addition, the limitation 'the cutaneous depression, wound, fissure, or opening is selected from diverticulae, cysts, fistulae or aneurysms' in new claim 213 is not supported by the as-filed specification. See MPEP § 2163.06. Applicants cite page 20, line 20-page 21, line 6 of the instant specification for support of the new limitation. However, page 20 and 21 do not provide support the limitation in new claim 213. These pages only provide support for cutaneous depression.

Thus, nothing in the specification would lead one to the particular combination set forth in the amended claim 107 and claims dependent therefrom and new claims 154-217 set forth in the instant application. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.,* 41 USPQ2d 1961, 1966 (CAFC 1997).

Claims 156, 162, 165, 172, 192, 203, 208, and 217 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using MDCs in a method of augmenting or bulking muscle tissue in a recipient; and does not reasonably provide enablement for using the cells in a genus of therapeutic methods contemplated by the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is directed to using MDCs to treat an injured, damaged, or dysfunctional muscle tissue (skeletal or smooth) in a recipient. The invention lies in the field of cell therapy.

The art of record for cell transplantation (e.g. myoblast) has been hindered by various limitations: immune rejection, poor cellular survival, and the limited spread of the injected cells (Lee et al., The Journal of Cellular Biology, Vol. 150, 2000, pp. 1085-1099, IDS). Lee further teaches that, "skeletal muscle tissue has been extensively investigated as a potential source for isolation of pluripotent stem cells. A recent report has suggested that only a discrete minority of myoblast can survive after implantation and thus may represent a population of myogenic stem cells. In 1998, a specific population of highly purified muscle derived cells by the pre-plate technique that significantly improved cell survival after transplantation when injected intramuscularly." Although the mechanism by which these specific muscle derived cells display a high cell survival is unclear (page 1086). "Comparison of the muscle-derived cells to other types of muscle-derived cells indicates that more studies are required to accurately assess the origin and more importantly, the functional property of these various populations of muscle-derived stem cells (page 1096-1097)."

In addition, the art of record teaches, "the study of muscle satellite cells as a stem cell and it role in skeletal muscle is still in its infancy and it will now be important to characterize the influence of growth factors and components of the extracellular matrix responsible for activating genetic responses within stem cells (Seale et al., Developmental Biology, 2000, page 122, IDS)." Thus, at the time the application was filed, the art of record for the production or isolation of a genus of muscle-derived progenitor cells was considered unpredictable.

The specification provides working examples briefly described below:

Example 1 teaches the preparation of mouse muscle derived cells (MDC), pp6 (pages 28-30). Examples 3-5 and 7-8 display that genetically modified MDC with Lac Z were viable for up to 4 weeks in the lower abdomen of rats as shown in Example 3 (pages 32-33 and 39-40). Example 6 displays an increase in the contraction amplitude and contraction velocity of bladder strips of cryodamaged bladder tissue in rats using MDC (pages 33-39). Example 9 displays that genetically modified mc13 cells with adBMP-2 can cause bone formation (pages 40-51).

With respect to the claimed methods (claims 156, 162, 165, 172, 192, 203, 208, and 217), the specification only enables one skilled to use MDCs in a method of augmenting or bulking smooth muscle tissue or skeletal muscle tissue in a recipient. It would take one skilled in the art an undue amount of experimentation to reasonably correlate from the working examples to a genus of therapeutic methods in a recipient because of the lack of guidance for using a genus of isolated MDCs in the genus of claimed methods. Furthermore, the breadth of the instant invention as claimed embraces repairing injured, damaged or dysfunctional i) esophageal muscle tissue, ii) gastroesophageal, iii) sphincter muscle tissue, iv) ureteral-bladder muscle tissue, iv) heart muscle, or v) bladder tissue in a recipient by administering an undefined population of undifferentiated muscle derived progenitor cells (U-MDCs). However, the specification does not disclose a working example for each claimed method. The art of record teaches, "While much of the attention has been focused on bone and cartilage healing in orthopedic-related injuries, less emphasis has been directed to comprehending the normal and abnormal development of muscle tissue (Kasemkijwattana et al., Cell Transplantation, 7:585-598, 1998, IDS). The office conducted a prior art search of the claimed methods against prior art databases and the results

from the search did not display any cell therapy to treat injured, damaged or dysfunctional esophageal muscle tissue or gastroesophageal. Each muscle tissue embraced by the claimed invention has a different structure and function and the specification lacks guidance from correlating from the working examples to treating a genus of muscle tissue injuries or disorders. The as-filed specification fails to disclose that the injection of MDCs derived from any type of muscle (skeletal or smooth) into a recipient would lead to a treatment of an injured, damaged, or dysfunctional tissue. In addition, the specification fails to disclose that MDCs would provide immune protection to MDCs of xenogenic or allogenic origin. The art of record teaches that altering the immune system of the host could potentially affect the fusion of transplanted myoblast. Furthermore, immunosuppressive agents may be directly toxic to host muscle (Rando, IDS).

Furthermore, the specification fails to provide sufficient guidance for one skilled in the art to reasonably extrapolate from the specification to treating any muscle disorder embraced by the claimed invention. With respect to the working examples directed to treating stress urinary incontinence (SUI), the art of record teaches that SUI occurs when urethral sphincter muscle is not sufficiently strong to prevent urine leakage for example while coughing or jumping. SUI is associated most often with pelvic floor muscle laxity. Weakened and stretched out muscles and connective tissue lead to reduce muscle tensions in the sphincter complex that's insufficient to keep the urethra closed tightly when pressure increases. Furthermore, urinary incontinence is the result of mixed and urge and stress incontinence (Newman et al., Am. J. Nurs. 103:46-55, 2003). The uretheral afferent nerve activity affects the micturition reflexes, indicating that in patients with SUI, the leakage of urine proximal urethra stimulates afferent nerve, which facilitate

voiding reflexes (Jung et al., The Journal of Urology, 162:204-212, 1999). Furthermore, detrusor weakness is a slowly progressing problem in human, whereas the murine model as disclosed in the instant specification has only shown physical improvement following an acute cryo-induced injury. The state of SUI art teaches that the graft success and the physiological improvement observed in the rodent-model may be absent in chronic weakness usually associated with human (Huard et al., Gene Therapy 9:1617-1626, 2002). The Gene Therapy article (where Dr. Chancellor is one of the authors) recites that the graft success and the physiological improvement observed in the murine-model may be absent in chronic weakness usually associated with stress urinary incontinence in humans (supra). Furthermore, Lee et al., (Int. Urogynecol J, 14:31-37, 2003, where Dr. Huard and Dr. Chancellor are co-authors) teach, "There are limitations to this animal model in that rats are quadrupeds and do not normally exert the same forces on their pelvis as do human females."

Furthermore, the as-filed specification fails to provide teaching what would be the appropriate dose of muscle-derived cells per route of administration for a sustained and high enough level of expression of transplanted cells to treat each disorder embraced by the claimed methods.

The art of record displays the unpredictability of muscle-derived cells differentiating into a specific muscle tissue. Kasemkijwattana et al. (Cell Transplantation, 1998, IDS) discloses that although muscle injury is capable of healing, an incomplete functional recovery often occurs (abstract) and the best treatment for muscle injury has not yet been defined and the recommended treatment regimens for contusions have varied widely, depending on the severity of the injury (page 585).

Furthermore, Ledley, *Pharmaceutical Research*, Vol. 13, pp. 1595-1614, 1996 (cited on a previous PTO-892), discloses that "while transplantation of hepatocytes, pancreatic cells, myoblasts, epidermal cells, neuronal cells, synovial cells, and fibroblasts has been demonstrated in animals, these methods are not routinely available for treating any medical disease or disorder in any animal including humans (page 1596)."

In the absence of essential teachings specific to the making and using a genus of isolated muscle-derived progenitor cells, it would require an undue amount of experimentation for one skilled in the art to reasonably extrapolate from the specification to practicing the full scope of the claimed invention.

Therefore, considering the unpredictability in the state of SUI art and limited amount of guidance provided by the instant specification, it is highly unpredictable that the administration of MDCs (autologous or allogenic) would ameliorate injured, damaged or dysfunctional i) esophageal muscle tissue, ii) gastroesophageal, iii) sphincter muscle tissue, iv) ureteral-bladder muscle tissue, iv) heart muscle, or v) bladder tissue in a recipient.

In conclusion, the as-filed specification and claims coupled with the art of record at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable for using MDCs in a method of augmenting or bulking muscle tissue in a recipient. One skilled in the art would have to engage in a large quantity of experimentation in order to practice the full scope of the claimed invention based on the application's disclosure, the unpredictability and the problems in the art of record for using MDCs for treating a muscle disorder in a recipient.

Applicant's arguments filed 9/27/04 have been fully considered but they are not persuasive because the argument does not address the 112 enablement rejection. The argument is directed to how the claims are enabled for bulking or augmenting muscle tissue, which is not part of the enablement rejection in the instant office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 184-189 and 212-215 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "opening in an individual" in claims 184 and 212 is a relative term, which renders the claims indefinite. The term "opening in an individual" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of term are not defined because it is not apparent whether the term only encompasses wounds or other openings in an individual, e.g., mouth, ear, nose, skin pores, etc.

Claims 185-189 and 213-215 are rejected under 112 second paragraph because the claims depend from either claim 184 or claim 212.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 190, 191, 192, 193, 194, 196, 197, 199, 201-204, 206-210 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 5,667,778) taken with Law (US 6,261,832).

Atala teaches a method of treating conditions, which require the reconstruction of an anatomical area selected from the group consisting of gastrointestinal tract and urinary tract comprising injecting into a patient at a site in the anatomical area a suspension of smooth muscle cells in a biodegradable polymer solution (columns 12-14). The suspension can be injected via

syringe and needle directly into the site wherever a bulking agent is desired, i.e. soft tissue deformity (column 9). Atala further teaches the cells can be used to augment sphincter muscle tissue (columns 8-9). However, Atala does not specifically teach using skeletal muscle cells in the method.

However, at the time the invention was made, Law teaches a method of augmenting muscle tissue using myogenic cells (columns 6-7). Law teaches that myogenic cells can be selected from skeletal, smooth, or cardiac (column 7). Law teaches using the cells in cosmetic usage (column 12). Law teaches that cells can be used to replenish wounds (column 2).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law, namely to use skeletal myogenic cells in the method of augmenting or bulking bladder or sphincter muscle tissue. One of ordinary skill in the art would have been motivated to use skeletal muscle cells instead of smooth muscle cells in the method taught by Atala because Law teaches that either skeletal or myogenic cells can be used in a method of augmenting muscle tissue and the specification of the instant application does not teach an unexpected result using skeletal muscle cells compared to smooth muscle cells in the claimed methods.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law, namely to use skeletal myogenic cells in the method of ameliorating a cosmetic defect by augmenting or bulking smooth muscle tissue. One of ordinary skill in the art would have been motivated to use skeletal muscle cells instead of smooth muscle cells in the method taught by Atala because Law teaches that either skeletal or myogenic cells can be used in a method of augmenting muscle

tissue and the specification of the instant application does not teach an unexpected result using skeletal muscle cells compared to smooth muscle cells in the claimed methods.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 190-197 and 199-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala taken with Law as applied to claims 190-194, 196, 197, 199, 201-204, 206-210 above, and further in view of Li (US 5,206,028).

Atala and Law do not specifically teach using collagen sponge material as the carrier in the methods.

However, at the time the invention was made, Li teaches that collagen membranes having physical and biological properties, which make them extremely suitable and desirable for all types of medical use (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law in further view Li, namely to use a collagen sponge material in the method of augmenting or bulking muscle tissue. One of ordinary skill in the art would have been motivated to use collagen sponge material in the methods because Li teaches that collagen membranes are suitable and desirable for medical use because the maintain their overall bulk density.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 170-173, 175, 176, and 206-211 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 260-272 and 274-279 of copending Application No. 09/302,896. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '896 are drawn to a method of ameliorating weakness in the bladder muscle tissue using muscle derived cells. Therefore, the claims of the instant application and '896 are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 9/27/04 requesting that the rejection be held in abeyance until claims in the instant application have been deemed allowable is acknowledged.

Conclusion

It is noted that copending application 09/302,896 has been allowed, but not issued. When '896 is issued the provisional double patenting rejection will become an obviousness double patenting rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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